

Exhibit 1

Application No.: 10/511,229

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Docket No.: 404172000300

Docket No.: 404172000300
(PATENT)**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:
Ilaria CAPUA et al.

Application No.: 10/511,229

Confirmation No.: 9235

Filed: April 12, 2002

Art Unit: 1648

For: PURIFIED SUBFRAGMENT CODIFYING
FOR NEUROAMINIDASE, RECOMBINANT
NEUROAMINIDASE AND ITS USE IN
ZOOPROPHYLAXIS

Examiner: M. Hill

DECLARATION UNDER 37 C.F.R. 1.132

I, Dr. Ilaria Capua, hereby declare and state as follows:

1. I am Head of the Virology Department at Istituto Zooprofilattico Sperimentale delle Venezie, Padova, Italy and Head of the National, FAO and OIE Reference Laboratories for Avian Influenza and Newcastle disease.
2. My *curriculum vitae* is provided as Exhibit A.
3. I am an inventor of U.S. Patent Application No. 10/511,229 ("the '229 application"). I have read the '229 application, including the amended claims.
4. I have also reviewed the Office Action issued on February 17, 2009, including the references cited therein. I understand that my own earlier short communication, Capua et al., *Veterinary Record*, 2000, 147(26):751 ("the Capua communication"), was cited as a prior art against claims of the '229 application.

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5. I have reviewed the Capua communication. The Capua communication is completely silent about detecting viral infection in a bird which has already been subjected to vaccination by means of a heterologous vaccine, let alone any method by which this can be achieved.
6. Notably, at the time the '229 application was filed, the greatest challenge facing an ordinary skill in the art in the field of avian influenza control was not simply differentiating between vaccinated birds and unvaccinated birds that had been infected with the epidemic field virus strain of avian influenza. Rather, the more significant hurdle to overcome in order to develop an effective and commercially viable vaccine strategy was the provision of a vaccine that allowed the identification of vaccinated birds subsequently exposed to an epidemic field strain of the virus ("the healthy carriers"). Without such a test, vaccinated birds could effectively "hide" outbreaks of the live virus. In other words, there would be no way of detecting live virus outbreaks in a vaccinated population with serological methods.
7. There was no teaching in the prior art, however, about a sensitive and reliable antibody test which allows diagnosis of viral infection in birds vaccinated with a conventional vaccine. Due to the characteristics of the viral replicative cycle and the occurrence of serologic cross-reactions between neuraminidase groups (for example due to shared epitopes and steric hindrance), it was generally understood that an antigen binding test for neuraminidase would not confer sufficient sensitivity and specificity for a diagnostic test.
8. Furthermore, it was unpredictable how the vaccine-induced antibodies would interfere with the production of anti-neuraminidase antibodies following subsequent infection with the field virus strain.
9. In a bird vaccinated with a vaccine containing a homologous haemagglutinin (H) to the field virus, the haemagglutinin elicits an immune response that contains neutralising antibodies against the field virus. Neutralising antibodies prevent the main functions of the haemagglutinin (i.e. attachment of virus to cell, penetration of virus in cytoplasm) and

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therefore virus replication is impaired. If the field virus is unable to replicate, the neuraminidase of that field virus would not be synthesized, and therefore an immune response against that neuraminidase would not have been expected.

10. The '229 application teaches that vaccination in an animal with a heterologous vaccine having a homologous haemagglutinin (H) would still permit limited replication of the infecting field virus in the vaccinated bird. Such viral replication does not occur to the extent of causing clinical signs, disease or death, yet it allows birds to seroconvert, i.e., to produce antibodies against specific antigens. In other words, minimal, but essential degree of replication in the animal is sufficient to generate detectable levels of antibody against the neuraminidase subtype of the field strain although insufficient to compromise the health of the animal.
11. The fact that one can include an intentional slight antigenic mismatch between the vaccine and the field virus haemagglutinin molecules that facilitates the minimal degree of field virus replication and hence a detectable serological response would not have been predictable based on the teaching of the cited reference.
12. In addition, the high specificity and low level of cross reactivity among neuraminidases provided by the methods of the present invention would not have been predictable based on the teaching of the cited reference.

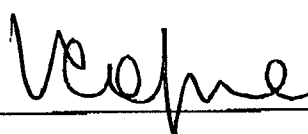
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13. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001 and that such willful, false statements may jeopardize the validity of the '229 application.

Date:

16. July. 2009.
Ilaria Capua

Ilaria Capua

Curriculum Vitae

Director of Virology Department

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e-mail	icapua@izsvenezie.it
Date of birth	21 st April, 1966
Place of birth	Rome, Italy
Nationality	Italian

CURRENT POSITION

She is currently Head of the OIE/FAO and National Reference Laboratory for Avian Influenza and Newcastle Disease and Head of the Research and Development Unit at the Istituto Zooprofilattico Sperimentale delle Venezie (IZSve), Padova, Italy. Since 1999 she has committed herself to Avian Influenza and Newcastle Disease outbreak management. In 2000 she developed the "DIVA" diagnostic system, a heterologous vaccination strategy for fighting avian influenza. This strategy, the first ever developed to combat avian influenza through vaccination, has been acknowledged and approved by the EU and OIE. Both as a veterinarian and virologist, in the course of her career she has been appointed as an FAO and OIE Expert for Avian Influenza and Newcastle Disease.

RECENT PROFESSIONAL ASSIGNMENTS

2007 – 2010

Member of the Networking Executive Committee of the US Centers of Excellence on Avian Influenza funded by NIH/NIAID

2006 – 2015

Member of the European Technology Platform for Global Animal Health (ETPGAH), which is responsible for the identification of priority research issues in the field of animal health.

2006 – 2013

Member of the Advisory Group to the EU Commissioner for Research on the EU 7th Framework Programme in the area “Food, Agriculture and Biotechnology”.

2003 – 2006

Member of the EFSA (European Food Safety Authority) Panel on Animal Health and Animal Welfare (AHAW”).

PROFESSIONAL ASSIGNMENTS

Since 1995 she has been invited by the European Commission to attend several meetings and workshops on viral diseases affecting birds and mammals, particularly on Avian Influenza, Newcastle Disease, Foot and Mouth Disease, Classical Swine Fever and Crimean Congo Haemorrhagic Fever. As a member of the EFSA (European Food Safety Authority) Panel on Animal Health and Animal Welfare (AHAW) she has participated in the drawing up of scientific reports issued by the European Commission on such diseases. She also participates in meetings with WHO, FAO and other organizations involved in outbreak management.

INTERNATIONAL INITIATIVES

In 2006 she launched the Global Initiative on Sharing Avian Influenza Data (GISAID), an international network for on-line sharing of Avian Influenza genetic data in the face of pandemic threats. The appeal to promote analysis and real-time exchange of available genetic data concerning Avian Influenza viruses was signed by researchers from over 30 countries, among whom 6 Nobel Prize Laureates, and was published in the journal *Nature* (August 24, 2006). Thanks to GISAID, the genetic sequences of Avian Influenza viruses will be gathered and made available for researchers from all over the world to better understand the pathogenic processes and the dynamics of outbreaks.

In 2005 she was appointed Head of the OFFLU project, an OIE/FAO network in support of countries affected by the Avian Influenza virus. The network promotes the exchange and analysis of virus strains responsible for the H5N1 outbreak and represents a link between the veterinary community and WHO. OFFLU will also provide researchers from developing countries affected by an epidemic with opportunities for specific training on disease diagnosis and prophylaxis.

EDUCATION

- ◆ University of Padova March 2007
PhD in Public Health, Veterinary Hygiene and Hygiene of Animal Production
- ◆ University of Pisa October 1991
Post-graduate diploma in Animal Health and Hygiene of Animal Breeding and Production
Final grades: 67/70.
- ◆ Qualifying examination for the practice of the veterinary profession, Perugia, 1989

- ♦ University of Perugia 1983 – 1989
Degree in Veterinary Medicine

PROFESSIONAL EXPERIENCE

- ♦ 1998 to present
Istituto Zooprofilattico Sperimentale delle Venezie, Legnaro (PD), Italy
Head of the OIE/FAO and National Reference Laboratory for Avian Influenza and Newcastle Disease
- ♦ 1997 – 1998 Istituto Zooprofilattico di Teramo, Italy
Appointed Head of the Virology Department and Research Centre for Exotic Diseases (CESME)
- ♦ 1994 – 1997 Istituto Zooprofilattico di Teramo, Italy
Appointed Head of the Virology Department and interim Head of Anatomy-Histopathology Department
- ♦ 1991 – 1994 Istituto Zooprofilattico di Teramo, Italy
Member of staff in the Diagnostic Virology Laboratory
- ♦ 1991 Istituto Zooprofilattico di Perugia, Italy
Consultant in the Serology Laboratory
- ♦ 1990 – 1991 Istituto Zooprofilattico di Perugia, Italy
1-year contract in the Serology Laboratory
- ♦ 1989 – 1990 Istituto Zooprofilattico di Perugia, Italy
Internship in the Diagnostic and Serology Laboratory

RESEARCH ACTIVITIES

She is currently involved in 28 national research projects and 11 international ones. Since 1993 she has coordinated a total of 45 projects.

International training and teaching experience

- ♦ FAO's TCP project coordinator. TCPs (Technical Cooperation Projects) are international training and cooperation projects whose aim is to train laboratory personnel for emergency avian influenza management and diagnosis. Under the supervision of Ilaria Capua, the Istituto Zooprofilattico Sperimentale delle Venezie was involved in one of these projects, which started in 2005, lasted for 18 months and involved 48 countries, subdivided into five main areas: Eastern Europe, the Middle East, Northern Africa, Eastern Africa and Western Africa. The training programmes lasted for one week and were attended by selected staff from the laboratories of the countries involved.
- ♦ Seminars and teaching activities:
 - ♦ University of Pennsylvania, Philadelphia, USA, 2006
 - ♦ University of Maryland, College Park, USA, 2006

- ♦ University of North Carolina, Raleigh, NC, USA, 2006
- ♦ Royal Swedish Academy, Stockholm, Sweden, 2006
- ♦ Utrecht University, Utrecht, The Netherlands, 2006
- ♦ University of Ghent, Belgium, 2003
- ♦ University of Vienna, Vienna, Austria, 2003
- ♦ University of Tokyo, Tokyo, Japan, 2002
- ♦ University of Atlanta, Georgia, USA, 2001
- ♦ University of Georgia College of Veterinary Medicine, Athens Georgia, USA, 2000
- ♦ Swedish Veterinary Institute, Uppsala, Sweden, 2000
- ♦ National Veterinary Institute, Pulawi, Polonia, 2000
- ♦ National academic appointments:
 - ♦ 2000 – 2002 Contract Lecturer in Avian Pathology at the University of Padova, Faculty of Veterinary Medicine
 - ♦ 1998 – 1999 Contract Lecturer in Avian Pathology at the University of Padova, Faculty of Veterinary Medicine
 - ♦ 1995 – 1997 Lectures on viral diseases in the framework of the course “Infectious Diseases of Domestic Animals” at the University of Teramo, Faculty of Veterinary Medicine

ORGANIZATION OF INTERNATIONAL CONFERENCES

- ♦ Organizer of the *Vaccination: a tool for the control of avian influenza* OIE/FAO/IZSve Conference, Palazzo della Gran Guardia, Verona, 20 – 22 March 2007
- ♦ Organizer of the 6th *International Symposium on Avian Influenza*, St John's College, Cambridge, UK, 3 – 6 April 2006
- ♦ Organizer of the *Joint OIE/WHO/FAO meeting on the H5N1 crisis*, Venice, 7 October 2005
- ♦ Organizer of the OIE meeting *Ad hoc group on AI for the updating of the Code Chapter on AI*, IZSve, Legnaro (PD), Italy, 8 – 10 November 2004
- ♦ Organizer of the 8th *Joint annual meeting of the Newcastle disease and Avian Influenza Reference Laboratories of countries of the EU*, IZSve, Legnaro (PD), Italy, 20 – 21 June 2002
- ♦ Member of the organizing committee of the *5th International Symposium on Avian Influenza*, Athens, Georgia, USA, 14 – 17 April 2002
- ♦ Organizer of the *Meeting of Member States' national experts for avian influenza on the development and application of an N1-N3 discriminatory test in the framework of the control of avian influenza through vaccination with a heterologous vaccine*, Legnaro (PD), Italy, 15 – 16 November 2001

CONFERENCE ATTENDANCE

Since 1998 she has participated as an invited speaker in 27 national conferences and in 64 international ones in Europe, Asia, Africa, North and South America. The complete list is reported in Annex 1 and is available from the secretarial staff.

LANGUAGES

English (fluent), German (conversational)

PRESS FEATURES

INTERNATIONAL NEWSPAPERS:

2006	March	The Wall Street Journal The New York Times
	April	Le Monde Liberation
	May	The Washington Post

INTERNATIONAL SCIENTIFIC JOURNALS/WEB PORTALS:

2006	February	Arzte Magazine
	March	Science
	November	Science Science and Development Network

INTERNATIONAL MAGAZINES:

2002	July-August- September	El Campesino
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PUBLICATIONS

She has participated in several OIE workshops for the revision of the chapters of the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals. Since 1990 she has authored over 300 publications, mainly concerning viral diseases of birds. These include articles published in international journals, conference presentations, editorials and book chapters. She is the co-author of an atlas on Avian Influenza. The complete list of her publications is available from her secretarial staff.

Publications in peer reviewed journals since 2000

- 2000 **Capua I.**, Mutinelli F., Terregino C., Cattoli G., Manvell R.J., Burlini F. (2000). "Highly pathogenic avian influenza (H7N1) in ostriches farmed in Italy". *Veterinary Record* 146, p. 356.
- Capua I.**, Marangon S. (2000). "Review article: The avian influenza epidemic in Italy, 1999-2000". *Avian Pathology*, 29, 289-294.)
- Capua I.**, Mutinelli F., Marangon S., Alexander D.J. (2000) "H7N1 Avian Influenza in Italy (1999-2000) in intensively reared chickens and turkeys". *Avian Pathology*, 29, 537-543.
- Capua I.**, Mutinelli F., Bozza M.A., Terregino C., Cattoli G. (2000). "Highly pathogenic avian influenza (H7N1) in ostriches (*Struthio camelus*)". *Avian Pathology*, 29, 645-648.
- Capua I.**, Mutinelli F., Campisi Lo Schiavo M., Dalla Pozza M., Ferré N., Manca G. (2000). Italian avian influenza epidemic. *International Poultry Production*, 8, 15-17.
- Capua I.**, Marangon S., Dalla Pozza M. (2000). "Newcastle disease in Italy". *Veterinary Record*. 146, (26): 768.
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- Capua I.**, Marangon S., Dalla Pozza M., Santucci U. (2000). "Vaccination for Avian Influenza in Italy". *Veterinary Record*, Dec 23-30, p 751.
- Capua I.**, Marangon S. (2000). "The Italian experience: what can we learn from it?" *World Poultry, Elsevier Special '00*, pp. 21-22.

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- 2001 Banks J., Speidel E. S., Moore E., Plowright L., Piccirillo A., **Capua I.**, Cordioli P., Fioretti A., Alexander D. J. (2001). "Changes in the haemagglutinin and the neuraminidase genes, prior to the emergence of highly pathogenic H7N1 avian influenza viruses in Italy". Archives of Virology. 146: 963-973.
- Capua I.**, Mutinelli F. (2001) "Mortality of Muscovy ducks (*Chairina moschata*) and domestic geese (*Anser anser var.domestica*) following natural infection with highly pathogenic avian influenza of the H7N1 subtype". Avian Pathology, 30 179-183.
- Herczeg J., Pascucci S., Massi P., Luini M., Selli L., **Capua I.**, Lomniczi B. (2001). "A longitudinal study of velogenic Newcastle disease virus genotypes isolated in Italy between 1960 and 2000". Avian Pathology, 30 163-168
- Cattoli G., Manvell R.J., Tisato E., Banks J., **Capua I.** (2001). "Characterisation of Newcastle disease viruses isolated in Italy in 2000". Avian Pathology 30 465-469.
- Terregino C., Montesi F., **I. Capua** (2001) "Detection of circovirus-like agent from farmed pheasants (*Phasianus colchicus*) in Italy". The Veterinary Record 15, p. 340
- Cattoli G., Terregino C., Brasola V., Rodriguez J.F., Zuin A., **Capua I.** (2001). "Utilizzo di un vaccino eterologo nei confronti dell'influenza aviaria come vaccino "marker": prova di cross-protezione e validazione preliminare del test discriminatorio". Large Animal Review, year 7, n. 6, December 2001. pp. 97-98
- Terregino C., Brasola V., Tramontan B., Buson D., Montesi F., **Capua I.** (2001). "Prova di cross-protezione nei confronti della variante bronchite infettiva 624/I utilizzando vaccini commerciali contenenti le varianti M41 e 793/B". Large Animal Review, year 7, n. 6, December 2001. pp. 99- 100.
- 2002 **Capua I.**, Cattoli G., Marangon S., Bortolotti L., Ortali G. (2002). "Strategies for the control of avian influenza in Italy". The Veterinary Record, February 16, p. 223.
- Capua I.**, Alexander D.J. (2002) "Avian Influenza and Human Health". Acta Tropica 83.
- Capua I.**, Mutinelli F., Dalla Pozza M., Donatelli I., Puzelli S., Cancellotti F.M. (2002) "The 1999-2000 Avian Influenza (H7N1) Epidemic in Italy: Veterinary and Human Health Implications". Acta Tropica 83
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- Capua I.**, Marangon S. (2002). "Avian Influenza in Poultry in Chile". The Veterinary Record, August 10, 151(6), 2002
- Capua I.** & Marangon S. (2002). "DIVA was a successful strategy to eradicate Avian Influenza in Italy". World Poultry – Elsevier Vol. 18, N° 7 '02, pp. 44 –45
- 2003 **Capua I.**, Marangon S., Terregino C. and Cattoli G. (2003). "The Avian Influenza Experience – AI in Italy 1997-2002". Canadian Poultry, Volume 90, Number 2, pp. 30-46 February 2003.
- Capua I.**, Terregino C., Cattoli G., Mutinelli F. and Rodriguez J.F. (2003). "Development of a DIVA (Differentiating Infected from Vaccinated Animals) strategy using a vaccine containing a heterologous neuraminidase for the control of Avian Influenza". Avian Pathology, Vol. 32, pp. 47 –55
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- Cattoli G., Terregino C., V. Brasola, J.F. Rodriguez, **Capua I.** (2003). Development and preliminary validation of an ad hoc N1-N3 Discriminatory test for the control of avian Influenza in Italy." Avian Diseases. Special Issue 2003. pg 1060 –1062.
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- Capua I.**, Marangon S., Cancellotti F.M. (2003). "The 1999–2000 Avian influenza H7N1 Epidemic in Italy" . Veterinary Research Communications, 27 Suppl. 1 (2003) 123-127.
- 2004 **Capua I.**, Alexander D.J. (2004). "Human Health Implications of Avian Influenza Viruses and Paramyxoviruses". Eur J. Clin. Microbiol. Infect Dis. (2004) 23:1-6.
- Capua I.**, Terregino C., Cattoli G., Toffan A. (2004). "Increased Resistance of Vaccinated Turkeys to Experimental Infection with an H7N3 Low Pathogenicity Avian Influenza Virus". Avian Pathology (April 2004) 33(2), 158-163.
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- Capua I.**, Cattoli G., Marangon S. (2004). "DIVA" – A vaccination Strategy Enabling the Detection of Field Exposure to Avian Influenza Infections in Poultry". OIE-IABs International Conference. International Conference on the Control of Infectious Animal Diseases by Vaccination. Developments in Biologicals, Vol. 119, pp. 229-233
- Cattoli G., Vascellari M., Corro M., **Capua I.**, Mutinelli F., Sells S. F., Donahue J.M. (2004). "First case of equine nocardiform placentitis caused by Crossiella equi in Europe". Short Communications. The Veterinary Record, June 5, 2004, pp. 730-731.
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- Capua I.**, Marangon S. (2004). "Vaccination for avian influenza in Asia". Vaccine 22 (2004) pp. 4137-4138.
- Capua I.**, Alexander D.J. (2004). "Avian Influenza: recent developments". Review article, Avian Pathology (August 2004) 33(4), pp. 393-404.
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- Capua I.**, Alexander D.J. (2004). "An update on avian influenza in poultry". Elsevier, 1263 (2004), 741-744.
- 2005 Cattoli G., Toffan A., De Battisti C., Salviato A., Terregino C., **Capua I.** (2005). "Astroviruses found in the intestinal contents of guinea fowl suffering from enteritis". Letters, The Veterinary Record, February 12, 2005, p.220
- Terregino C., Cattoli G., De Nardi R., Beato M.S., **Capua I.**, Guberti V., Scremin M. (2005). "Isolation of influenza A viruses subtype H7N7 and H7N4 from waterfowl in Italy". Letters, The Veterinary Record, February 26, 2005, p. 292
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- Beato M.S. , De Battisti C., Terregino C., Drago A., Capua I., Ortali G. (2005). "Evidence of circulation of a Chinese strain of infectious bronchitis virus (QXIBV) in Italy". Letters, The Veterinary Record, May 28, 2005, p.720.

- Beato M.S., Terregino C., De Nardi R., Toffan A., Cattoli G., **Capua I.** (2005). "Epidemiological study on circulation of infectious Bronchitis Virus strains in North Eastern Italy". *Italian Journal of Animal Science* – 3/05, pp. 263-265.
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- 2006 **Capua I.** (2006). "Avian Influenza – past, present and future challenges". *Developments Biologicals*, Vol. 124, pp. 15-20.
- Cattoli G., **Capua I.** (2006). "Molecular diagnosis of avian influenza during an outbreak", *Developments Biologicals*, Vol. 124, pp. 99-105.
- Marangon S., **Capua I.** (2006). "Control of AI in Italy: from stamping out to emergency and prophylactic vaccination", *Developments Biologicals*, Vol. 124, pp. 109-115
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- Monne I., M.S. Beato, **Capua I.** (2006). "Pigeon paramyxovirus isolated from a robin in Italy", *Letters, The Veterinary Record*, March 18, p. 384
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- Cattoli G., Milani A., Bettini F., Beato M.S., Mancin M., Terregino C., **Capua I.** (2006). "Development and validation of anti-N3 indirect immunofluorescent antibody test to be used as a companion diagnostic test in the framework of a "DIVA" vaccination strategy for avian influenza infections in poultry", *Avian Pathol.*, Vol. 35(2), pp. 154-159
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Co-editor with D.J.Alexander of the atlas "Avian Influenza and Newcastle Disease. A field and laboratory manual" published by Springer in 2009.

AWARDS

Revolutionary Mind prize by Seed magazine in 2008 for leadership in policy for promoting sharing of information at an international level.

Scientific American 50 Award for being a policy leader for encouraging the free sharing of information about avian influenza, USA, 2007

Houghton Trust Lecturer 2005, Istanbul, Turkey, 23 August 2005

Donne Eccellenti, Abano Terme (PD), Italy, December 2005

Nomination for the Institute de France *International Louis D. Award*, March 2007 by the Accademia Nazionale dei Lincei, Rome, Italy, for outstanding work on the theme "Fighting Zoonoses".